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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,823	07/24/2006	Peter Kinast	19497-002US1	8435

26191 7590 10/22/2010
FISH & RICHARDSON P.C. (TC)
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EXAMINER

CARPENTER, WILLIAM R

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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10/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/542,823	Applicant(s) KINAST ET AL.	
	Examiner WILLIAM CARPENTER	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-60 and 62-105 is/are pending in the application.
- 4a) Of the above claim(s) 88-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-60 and 62-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/13/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 56-58, 60, 62-64, 76, and 78-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") in view of USPN 2,697,438 ("Hickey").

Regarding Claims 56, 58, 60, 76, 78, and 79, Henderson discloses a needle (10) **for** repeatedly penetrating a membrane having a pointed end (Fig. 2) provided with a penetrating tip (Fig. 3) and with an opening (13) for letting a liquid in and out in a main direction which is substantially parallel to the longitudinal extension of the needle (Fig. 2). Henderson discloses that the penetrating tip is designed with a point (12) to initially prick a membrane when the membrane is penetrated and that the outer edges present on the pointed end in the area from the point to a position beyond the opening are

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rounded (Figure 6) so that after the initial penetration the pointed end will push the membrane material away rather than cutting the membrane material (Col. 1, Ln. 50-63; Col. 2, Ln. 22-46). Henderson discloses the penetrating tip to be designed with a circular cross section having a symmetry (Fig. 6 and Fig. 2) at a longitudinal center line of the needle (when viewed from above, i.e. along the center line, as in Fig. 2). However, Henderson fails to disclose that the point is on the longitudinal center line when observed from all viewing angles, although this is not generally found to be necessary with respect to the independent Claim 56 or 76.

Hickey discloses a needle (1) designed to prevent coring (Title), a task mutually shared by the needle of Henderson. Hickey discloses that shape of the penetrating tip (Fig. 2) of the needle should be altered such that the point (5) of the needle lies directly on the longitudinal center line (A) of the needle (Fig. 2). Hickey discloses that the "location of the penetrating point at the axis of the cannula also reduces the tendency to coring" (Col. 2, Ln. 23-25). It would have been obvious for one having ordinary skill in the art at the time the invention was made to alter the shape of the penetrating point of the needle of Henderson such that the point lies on the longitudinal axis when observed from all viewing angles, as disclosed by Hickey, thereby only achieving the expected results of providing a needle penetrating tip shape that is art recognized for preventing needle coring.

While neither Henderson nor Hickey disclose the distribution of forces about the penetrating tip radiating from the longitudinal center line, it is held that the position of the modified point of Henderson in conjunction with the disclosed circular symmetry of the

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penetrating tip, that an infinite number of substantially equally sized forces in different directions radial to the longitudinal center line would be produced, the forces counteracting one another such that the needle will tend not to deviate from the initial penetration direction when the needle penetrates a membrane. It is important to note that it is not possible for the Office to perform experimental testing of both Applicant's claimed invention and those in the prior art in order to definitively ascertain the exact distribution of forces. As such, Examiner must rely upon the claimed structure in order to differentiate whether or not the prior art is capable of satisfying the claimed functional language. As the device of Henderson, as modified by Hickey, discloses the same structure as claimed by Applicant, absent any explicit showing of evidence to the contrary, it is held that the prior art of Henderson and modified by Hickey is capable of satisfying the claimed functional language.

Regarding Claim 57, Henderson discloses that the inner edge of the opening is rounded (Fig. 6).

Regarding Claims 62, 80, and 81, both Henderson and Hickey discloses the pointed end to have a shape substantially corresponding to part of an imaginary cone, the tip of which coincides with the point (Fig. 3; Henderson) (Fig. 2; Hickey).

Regarding Claims 63 and 82, both Henderson and Hickey discloses that the opening is formed such that a opening thereof is arranged on one and the same half of the cross-section of the needle (Fig. 2 and 3; Henderson) (Fig. 2 and 3; Hickey). It is important to note that the cross-section of the needle may be assumed at any position.

Regarding Claims 64 and 83, Henderson illustrates the pointed end to be provided with a basic shape in accordance with a lancet bevel cut (Fig. 2).

4. Claims 59 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") and US Patent No. 2,697,438 ("Hickey") as applied to Claim 58 or 76 above, and further in view of and US Patent No. 4,889,529 ("Haindl").

Regarding Claims 59 and 77, Henderson in view of Hickey discloses the invention substantially as claimed except that the cross section is substantially triangular with rounded edges. However, Haindl discloses a needle (30) specifically designed as to be non-coring (Abstract). Haindl discloses that the needle should have a penetrating tip (Fig. 5) having a cross section that is substantially triangular with rounded edges (33). It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the cross section of the penetrating tip of the modified device of Henderson having a substantially triangular cross section with rounded edges, as disclosed by Haindl, thereby only achieving the expected results of providing a needle having a penetrating tip shape that is explicitly disclosed as preventing coring.

5. Claims 65 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson") and US Patent No. 2,697,438 ("Hickey") as applied to Claims 56 or 58 above, and further in view of and US Patent No. 5,515,871 ("Bittner").

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Regarding Claims 65 and 84, Henderson discloses the invention substantially as claimed except that pointed end is provided with a basic shape in accordance with a back bevel cut. However, Bittner discloses various needles (10, 2, and 30) having either a lancet bevel (Fig. 3) or a back bevel (Fig. 2), illustrating the two bevels to be obvious variants of one another. As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to modify the tip of the needle of Henderson to comprise a back bevel, as disclosed by Bittner, thereby only achieving the expected results of replacing one needle point end bevel with an art recognized alternative bevel.

6. Claims 66-69, 72, 73, and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson"), US Patent No. 2,697,438 ("Hickey"), and US Patent No. 5,515,871 ("Bittner") as applied to Claims 58, 65, or 84 above, and further in view of US Patent No. 4,889,529 ("Haindl").

Regarding Claims 66, 68, 72, 73, and 86, Henderson in view of Hickey and Bittner discloses the invention substantially as claimed except for explicitly disclosing the angle of the back bevel cut. However, Bittner does illustrate the back bevel cut to be to the order of 45 degrees (Fig. 2B). Haindl illustrates a similar needle (60) which explicitly has a point bevel of 30 degrees (Fig. 8). As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the modified needle of Henderson to include a beveled point of 30 degrees, as disclosed by Haindl, thereby only achieving the expected results of providing a well-known tip bevel

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angle to obtain a predictable outcome. It has been held that a value within a range anticipates said range.

Regarding Claims 67 and 69, Henderson in view of Bittner and Haindl discloses the invention substantially as claimed except that bevel cut has a tip angle in the interval of 50 to 100 degrees. However, one having ordinary skill in the art would reasonably recognize and appreciate that the tip angle is a result effective variable as established by Bittner and more specifically Haindl. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the bevel cut of the modified device of Henderson to be within an interval of 50 to 100 degrees and more specifically to approximately 75 degrees, since it has been held that discovering the optimum value of a result effective variable requires only routine and customary skill in the art.

7. Claims 70, 71, 74, 75, 85, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,064,651 ("Henderson"), US Patent No. 2,697,438 ("Hickey"), and US Patent No. 5,515,871 ("Bittner") as applied to Claims 56, 65, 69 or 84 above, and further in view of US Patent No. 6,517,523 ("Kaneko").

Regarding Claims 70, 71, 74, 75, 85 and 87, Henderson in view of Hickey Bittner and Haindl discloses the invention substantially as claimed except for disclosing the second grind angle of the back bevel cut. However, Kaneko discloses a needle (1) having a second grind angle of between at least 115 to 135 degrees (Figure 1C), thereby establishing the second grind angle as a result effective variable. However, Kaneko fails to explicitly disclose that the second grind angle is limited to the interval of

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50 to 140 degrees, and more specifically to about 100 degrees. It would have been obvious for one having ordinary skill in the art at the time the invention was made to form the second grind angle of the modified device of Henderson to comprise a second grind angle of approximately 100 degrees, within the range suggested by Bittner, since it has been held that determining the optimum value for a result effective variable requires only routine skill in the art thereby only achieving the expected results of providing a suitable second grind angle for a needle to obtain a predictable outcome.

Response to Arguments

8. Applicant's arguments filed with respect to the claims have been fully considered but they are not persuasive.

Applicant argues that "Thus, the supposed advantage of positioning the point of the needle disclosed by Hickey along the longitudinal centre line of the needle is to facilitate the flow of fluid through the opening in combination with the curvature of the surfaces of the needle opening when the needle is pushed into and encased in solid skin tissue." However, this is not found to be persuasive. While Hickey does disclose that flow control is one advantage of the location of the needle point, Hickey also clearly identifies that the location of the needle point is of specific benefit in preventing coring, reciting "The location of the penetrating point at the axis of the cannula also reduces the tendency to coring" (Col. 2, Ln. 23-25). Even presuming, *ad arguendum*, that flow control was the only benefit as to the point position identified by Hickey, the fact that applicant has recognized another advantage which would flow naturally from following

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the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues that "A skilled person would therefore have no reason to provide a needle for repeatedly penetrating a vial membrane with a point located along the longitudinal centre line of the needle, since the problem solved by such a feature of Hickey's disclosure does not occur when merely penetrating the membrane of a vial". However, this is not found to be found persuasive. Henderson discloses a specific needle configuration designed to prevent coring. Hickey discloses a specific modification disclosed to prevent coring. Therefore, it would have been obvious for one having ordinary skill in the art at the time the invention was made to modify the needle of Henderson, as disclosed by Hickey, in order to better prevent coring. Examiner notes that penetrating a "membrane of a vial" is not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, such a recitation by Applicant constitutes mere functional language drawn towards the intended use of the device. A recitation of intended use only limits the claims inasmuch as the prior art must be capable of performing that particular function. Whether or not the references of Henderson and Hickey recognize that this particular needle configuration would have particular use in penetrating a vial membrane is inconsequential as such a specific recitation is not required by the metes

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and bounds of the claims. The only requirement is that the resultant invention is capable of performing such a use, which the combination of Henderson and Hickey is indeed.

Applicant argues that "one of ordinary skill would not seek to provide the needle disclosed by Henderson with a point that lies along the longitudinal centre line of the needle as this would entail an additional manufacturing step." However, this is not found to be persuasive. Hickey provides clear and distinct motivation for providing a needle with a point that lies along the longitudinal center line when viewed along all angles in order to prevent coring. Regardless of whether or not such a modification to the Henderson reference would add an additional manufacturing step in inconsequential as this "additional manufacturing step" would be met with a distinct improvement as to the functioning of the device. One having ordinary skill in the art would have obviously modified the disclosed manufacturing process of the modified invention of Henderson, in view of Hickey, in order to form the resultant invention in the most efficient manufacturing process.

Applicant argues that "a person having ordinary skill in the art reading the Henderson and Hickey references would have understood that these references disclose two different types of hypodermic needles for avoiding tissue coring". However, this is not found to be persuasive. One having ordinary skill in the art would recognize that the two references teach a plurality of techniques and features that can be used to prevent coring. As such, one having ordinary skill in the art would be compelled to try creating a combination device that utilizes these plurality of features to create a superior non-coring needle.

Applicant argues "there is no logical reason why a person having ordinary skill in the art reading the Henderson and Hickey references and setting out make a hypodermic needle that avoids tissue coring would modify the needles of Henderson or Hickey as the Examiner appears to contend for the simple reason that the hypodermic needles of both Henderson and Hickey already avoid tissue coring". However, this is not found to be persuasive. One having ordinary skill in the art, reading the reference of Hickey, would reasonably recognize and appreciate that the specific features taught by Hickey to be non-coring could be beneficially added to the invention of Henderson in order to further combat coring with suitable, well-known and art-recognized features.

Applicant argues that "the non-coring advantages of the Hickey needle is attributed to the combination of surfaces 8 and 10 and the axial location of the penetrating point". However, this is not found to be persuasive. While Hickey discloses a combination of features that together create a non-coring needle system, Examiner submits that one having ordinary skill in the art would reasonably recognize and appreciate that any of the features alone could be used to improve similar needles to provide a more complete, non-coring system. As such, one having ordinary skill in the art would look at the particular feature set of the Hickey reference to further improve the Henderson reference and further decrease the potential for coring. Any combination of these features sets would have been obvious for one having ordinary skill in the art, and any specific combination would have been the inevitable result of finite number of combinations of these particular features.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
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/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767